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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/717,088
Filing Date: November 22, 2000
Appellant(s): KO, THOMAS SAI YING

GORDON KIT
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 10, 2004 appealing from the Office action mailed April 9, 2003.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The status of claims has changed since the time of the filing of the brief. Examiner had indicated allowable subject matter during telephone interview with the attorney of record on October 31, 2005. A correct statement of the status of the claims is as follows:

Claims 35 and 36 are allowed.

Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This appeal involves claims 22-32, 34, 37, and 38.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

3,987,000	GLEICHENHANGEN et al.	5-1971
5,632,727	TIPTON et al.	5-1997
5,708,023	MODAK et al.	1-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-32, 34, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleichenhagen et al. (US 3987000) in view of Tipton et al. (US 5632727) and/or Modak et al. (US 5708023).

Gleichenhagen teaches sprayable polymer compositions. The reference teaches that sprayable polymer compositions for formation of a film over a wound area are usually formed in solvents such as ethyl acetate, acetone, or ethanol. See col. 1, lines 33-65. Such films contain polymers such as acrylic acid and methacrylic acid, as well

as softeners (plasticizers) such as phthalates. See col. 1, lines 45-48. Acrylic acid and methacrylic acid are taught as preferred monomers for the compositions of Gleichenhagen. See col. 4, lines 17-25. The reference further teaches the use of additional antiseptic or bacteriostatic substances. See col. 6, line 65 – col. 7, line 2. While the reference differs from the instant claims with respect to concentrations of components, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233, 235 (C.C.P.A. 1955).

While the reference generally teaches the use of active substances in combination with the sprayable polymer compositions, the reference lacks the scope of active agents as claimed, particularly cetrimide, chlorbutanol, and triclosan.

Tipton teaches a biodegradable film dressing and an apparatus for the spray delivery of the dressing. See col. 4, line 41 – col. 6, line 7. The biodegradable film can be used to protect and to promote healing of injured tissue and to deliver biologically active agents. See col. 2, lines 24-48. Solvents used include acetone. See col. 6, lines 42-55. A water-soluble pore-forming agent can be included. See col. 7, lines 34-49. A water-soluble pore-forming agent can be included. See col. 7, lines 34-49. An antifungal agent for use in the composition includes tolnaftate. See col. 9, lines 28-67. Phthalic esters can be included as modifiers. See col. 10, lines 56-60.

Modak teaches a method of inactivating irritants in a fluid contacting skin comprising applying a composition to the skin. See col. 2, lines 19-62. The active antiirritant agents in the compositions of Modak include centrimide, chlorbutanol, and triclosan. See col. 4, line 46- col. 5, line 3.

It would have been obvious to one of ordinary skill at the time the invention was made to have modified the compositions of Gleichenhagen by the use of active agents such as tolnaftate, centrimide, chlorbutanol, or triclosan in order to benefit from the activities of such agents in topical wound dressings as taught by Tipton and/or Modak.

(10) Response to Argument

The main issue in this case is whether the obviousness rejection was properly made under 35 U.S.C. § 103 (a), when the primary evidence on which examiner had relied is the description of prior arts other than the invention of the cited patent.

It is well known in patent law that nonpreferred embodiment constitutes a prior art. The court in In re Heck held, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." See 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. See Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d

1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998). The court in In re Susi also held that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The court in In re Gurley stated, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)

In this case, appellant argues that Gleichenhagen teaches away from the present composition, which employs plasticizers, since the prior art invention is directed to a specific copolymer system which does not require addition of plasticizers. However, also disclosed in the Gleichenhagen reference is the fact that the polymers such as "polymethylacrylates and polyacrylates or their copolymers", polyvinyl acetate/vinyl chloride mixtures, and polyvinylpyrrolidone, have been used in making wound bandage. See col. 1, lines 33 – 64. The reference also teaches that the use of plasticizers to soften the film and to make it more flexible had been in practice. See Id. Thus a reasonable skilled artisan would have known from the Gleichenhagen teaching that it was well known to make liquid bandage by combining appellant's polymer(s) and plasticizers. While appellant asserts that the Gleichenhagen invention itself teaches away from the claimed invention, appellant's position is contrary to the precedents well established by the courts. The entire disclosure of the Gleichenhagen should be treated as the evidence that shows the obviousness of the present invention. Although Gleichenhagen describes that having to use plasticizer is disadvantageous, the

reference nevertheless teaches that such use had been known. The reference merely describes the polymer mixtures with a plasticizer as a nonpreferred embodiment, rather than teaches away from using a plasticizer.

Furthermore, Tipton also suggests using plasticizers to modify the rheology of a liquid wound dressing. The reference teaches in col. 10, lines 45 – 55,

> Depending on the desired properties of the film dressing, other additives can be incorporated into the liquid composition. Additives can affect both drug release and mechanical properties of the film. Such modifiers can be added in effective amounts to increase flexibility, to control permeability, to slow drug release, to increase percutaneous absorption of biologically active agents, and to monitor biodegradability. By way of example, the modifier triethyl citrate can be combined with the liquid composition to modify the function of the film by controlling permeability and to slow drug release.

Thus, the cited references provide sufficient evidence that the presence or absence of plasticizer in a polymer composition is not a nonobvious choice of a skilled artisan, but merely depends on the desired film property of the final product.

Appellant also asserts that Gleichenhagen relates to aerosol formulations only. Examiner respectfully points out that the claimed composition is a "sprayable" composition, which does not need a distinction as to whether it is sprayed by pump device or aerosol valve. A same composition may be non-aerosol sprayable or aerosol sprayable depending on the spray devices used, since it is not until the time of the delivery of the liquid composition that the propellants and the composition is mixed. See Tipton, col. 12, lines29 –33. Furthermore, examiner asserts that making an aerosol composition into a non-aerosol formulation is not a surprising or nonobvious invention. Tipton teaches in col. 1, lines 11-46, and particularly in lines 30 –36,

> The dispensing means can be any chemical, mechanical or electrical component which acts to propel the liquid composition as a liquid stream, liquid droplets or atomized spray from the vessel. The dispensing means can be a pump, a fluid pressurizing component, a collapsible vessel with a tube or jet, or an aerosol propellant with associated value mechanisms.

Thus, whether the liquid bandage is dispensed from a pump, non-aerosol or aerosol device does not change the structure of the composition itself nor would it have been a nonobvious invention.

Appellant asserts that Tipton et al. and Modak each fails to teach the claimed invention. In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the outstanding rejection is made over the disclosure of Gleichenhagen in view of Tipton and/or Modak, rather than the individual references. Making a liquid bandage with appellants' polymers in combination with plasticizers is already taught in Gleichenhagen. Tipton is cited to show that it is well known to incorporate to a liquid bandage formulation the specific drugs of instant claim 28.

Appellant's argument that the cited arts are "incompatible" is not persuasive. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, appellant asserts that Tipton is an "incompatible" art since it uses

biodegradable polymer and water in two-part formulation. In response, examiner asserts that the combination of the references is proper since these are analogous arts. Both Gleichenhagen and Tipton are directed to liquid wound dressing or bandage compositions that are sprayable, thus these references are in the field of appellant's endeavor. Modak teaches using anti-irritants in topical drugs, which is also pertinent to the particularly problem which appellant is concerned.

Appellant asserts that examiner is in error in stating that "simply because two references are in the same technical field the teaching of the same can be combined regardless of their incompatibility". Examiner notes that the ground of the rejection is not that the Gleichenhagen and Tipton compositions would be physically incorporated all together as appellant asserts. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Appellant also asserts that the references are incompatible because Gleichenhagen does not mention adding antifungal component, whereas Tipton teaches tolnaftate, an antifungal agent. The argument is unpersuasive. Gleichenhagen teaches adding antiseptic or bacteriostatic substances. Claim 17, the broadest claim, is not even limited to any specific type of active agent. Tipton teaches not only antifungal agents but anti-bacterial agents as well, and in fact teaches, "The delivery system can

contain a large number of biologically-active agents either singly or in combination". See col. 9, line 33 – col. 10, line 26. Thus adding tolnaftate to a liquid wound bandage compositions that are described in Gleichenhagen would have been obvious to the skilled artisan.

Finally, examiner reiterates that the description of other prior arts in Gleichenhagen is a part of the teaching of the patent. See In re Heck. While Gleichenhagen invention itself is directed to a polymer composition that does not require plasticizers, the reference nevertheless teaches that it had been a well-known and obvious practice to employ plasticizers with certain polymers such as those used by appellants in order to soften the film formed. An old and well-known composition should not be patented just because a prior art describes it as an outdated invention and teaches ways to improve it.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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